DEPARTMENT OF HEALTH AND HUMAN SERVICES

913491d

Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

June 7, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN2001-025

Craig E. Sallin, Owner
Good For You America
501 Myrtle Street
Syracuse, NY 13204

Dear Mr. Sallin:

An inspection of your firm known as Food Reserves, Inc., 110 Bismark Street, Concordia, Missouri on March 8-19, 2001 revealed that your firm manufactures various meal replacement food products. Our review of information for the products The Original Food Tab, Survival Tabs, and Maca Manna reveals that the products are in violation of Section 402, 403 and 505 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling, as follows:

The Survival Tabs and all flavors of The Original Food Tab products are adulterated under Section 402(a)(2)(C) of the Act because they contain cholecalciferol (vitamin D_3), which is an unapproved food additive when used in these types of products. Vitamin D_3 has been affirmed to be generally recognized as safe when used in accordance with 21 CFR 184.1950. However, because of safety concerns raised by a cumulative dose that could result from multiple additions to foods, that regulation restricts use to the limitations specified, in accordance with 21 CFR 184.1(b)(2) which states: "Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation."

The product Maca Manna is misbranded under Section 403(q)(1) of the Act because the label bears a "Supplement Facts" panel instead of a "Nutrition Facts" panel (21 CFR 101.9).

The products The Original Food Tab (Strawberry Flavor, Butterscotch Flavor, Malt Flavor and Vanilla Flavor) are misbranded under Section 403(q)(1) of the Act because the labels bear nutrition labeling in the old format (21 CFR 101.9).

CRP:all

In addition, the Maca Manna label contains the claims "Hormonal balance and rejuvenation (Avoid HRT)" and "Protection against vaginal infection." The brochure for Maca Manna contains the claims "...eradicates invasive pathogens," "if the bad flora take over, we have poor health," "we know that antibiotics kill all flora, good and bad. So, it is especially important to replenish the supply of good flora after taking drugs, before the bad flora gets a hold," "cancer preventing nutrients," "...use it to treat numerous problems and diseases...male impotence, infertility and osteoporosis...for memory disorders...," "supplants hormone replacement therapy," "increase bone density, combats osteoporosis," "protects against vaginal infection," aids in correcting and preventing prostatitis." These are not structure/function claims under Section 403(r)(6) of the Act, and 21 CFR 101.93(g), but instead are disease claims.

Based on the labeled claims for this product and its intended use, the product is a drug under Section 201(g) of the Act. It is also a new drug under Section 201(p) of the Act and may not be legally marketed in the United States without an approved New Drug Application as required under Section 505(a) of the Act.

Furthermore, this drug is also misbranded under Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the product is safe and effective for its intended uses when, in fact, this has not been established.

Most of the above violations concern certain new labeling requirements, and are not meant to be an all-inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are manufactured and labeled in compliance with all applicable statutes and regulations enforced by FDA.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your dietary supplements.

It is necessary for you to take action on these matters now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Mary Woleske for

Charles W. Sedgwick
District Director
Kansas City District

cc: Joyce J. Axtell, Manager
Food Reserves, Inc.
110 Bismark Street
Concordia, MO 64020